UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,031	12/29/2000	Lucas J.C. Van Loon	276550 BO-43213 ACW	6442

22242 7590 04/08/2003

FITCH EVEN TABIN AND FLANNERY
120 SOUTH LA SALLE STREET
SUITE 1600
CHICAGO, IL 60603-3406

EXAMINER
DAVIS, RUTH A

ART UNIT	PAPER NUMBER
1651	6

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/750,031	SIEMENSMA ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's amendment filed December 30, 2002 has been received and entered into the case. Claims 17 – 41 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Objections

Claim objections are withdrawn due to amendment.

Claim Rejections - 35 USC § 112

Rejections under 35 U.S.C. 112, second paragraph, are withdrawn due to amendment.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 17 – 22, 24 – 33 and 35 – 41 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Khan.

Applicant claims a composition comprising carbohydrate material, peptide material and two free amino acids consisting of leucine and phenylalanine wherein the amino acids are present at 0.2 – 20 wt %, between 1 – 10wt % or at least 7%. The composition further comprises additional free amino acids selected from arginine or glutamine in amounts of 0.1 – 20 wt %. The peptide material is derived from wheat, rice, pea, casein, whey proteins or mixtures thereof and is obtained by hydrolyzing protein material. The peptide has an average peptide chain length of 20 – 40 amino acids or 3 – 20 amino acids and is present in amounts of 0.1 – 50 wt % or 2 – 25 wt %. The carbohydrate material is selected from monosaccharides, disaccharides or oligosaccharides, specifically a complex edible carbohydrate comprising maltodextrine and is present in amounts of 10 – 90 wt % or 50 – 80 wt %. The composition further comprises at least one of vitamins, flavors, minerals, lipids, and proteins and is an isotonic beverage or sports bar. Specifically, the composition contains 10 – 90 w % carbohydrate, 0.1 – 50 wt % peptide material and 0.2 – 20 wt % of each free amino acid. Applicant additionally claims a method of feeding and a method of enhancing blood insulin levels, the methods comprising administering the composition of claim 17, 36, 37 or 38 to a human.

Kahn teaches compositions containing casein and/or soy protein hydrolysates combined with whey protein hydrolysates and amino acids (abstract). The hydrolysates are obtained by

hydrolysis of the protein (p.2 line 15-20). The whey protein hydrolysate comprises 40 – 60 wt % if its amino acids as oligopeptides having 4 – 10 amino acids (p.4 line 5-10). The amino acids are in free form and comprise less than 3.5 % by weight (p.5 line 14-20) and may include arginine, glutamine, leucine and phenylalanine (p.8 line 30-50). The composition further includes carbohydrates (particularly maltodextrines p.6 line 8-9), fatty acids (triglyceride oils and phospholipids, p.6 line 25), vitamins, minerals (p.5 line 54-56) and flavorants (p.6 line 53). The compositions are disclosed for enteral use as well as aqueous liquids, food supplements, complete diet and therapeutic nutrition (p.6 line 12-19).

Kahn does not teach the composition comprising the specific amounts of carbohydrates, protein and amino acids or peptide chain lengths as claimed. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such variables as a matter of routine experimentation. Moreover, one of ordinary skill in the art would have been motivated by routine practice to optimize the volumes of Kahn with a reasonable expectation for obtaining a healthful, nutritious composition. Although the reference does not specifically teach a method for enhancing blood insulin levels, it was well known in the art that ingestion of carbohydrates, peptides and certain amino acids increase blood insulin levels (see Portman abstract). As such at the time of the invention, it would have been obvious to one of ordinary skill in the art to use the composition of Kahn in a method to increase blood insulin levels with a reasonable expectation of success.

Applicant argues that Kahn does not teach adding additional free leucine and phenylalanine with the peptide material, but that the amino acids are present in the hydrolysate

therefore there is no motivation to add additional amino acids. Applicant additionally argues a synergistic effect when the additional free amino acids are added to a wheat hydrolysate pointing to the third study in the specification.

However, these arguments fail to persuade because Kahn specifically teach free amino acids (p.5 line 14-20) including leucine and phenylalanine (p.8 line 30-50). In addition, at the time of the invention, free amino acids were known to stimulate glycogen synthesis (see Portman, abstract).

Regarding the synergistic effects, the claims do not include all of the limitations as described in the third study (i.e. wheat hydrolysate), and is therefore not commensurate in scope with the claims.

For theses reasons the claims remain rejected.

4. Claims 71 – 41 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Kahn in view of Kingham.

Applicant claims a composition comprising carbohydrate material, peptide material and two free amino acids consisting of leucine and phenylalanine wherein the amino acids are present at 0.2 – 20 wt %, between 1 – 10wt % or at least 7%. The composition further comprises additional free amino acids selected from arginine or glutamine in amounts of 0.1 – 20 wt %. The peptide material is derived from wheat, rice, pea, casein, whey proteins or mixtures thereof and is obtained by hydrolyzing protein material. Specifically, the peptide is derived from wheat protein. The peptide has an average peptide chain length of 20 – 40 amino acids or 3 – 20 amino

acids and is present in amounts of 0.1 – 50 wt % or 2 – 25 wt %. The carbohydrate material is selected from monosaccharides, disaccharides or oligosaccharides, specifically a complex edible carbohydrate comprising maltodextrine and is present in amounts of 10 – 90 wt % or 50 – 80 wt %. The composition further comprises at least one of vitamins, flavors, minerals, lipids, and proteins wherein the lipid is an emulsifier, and is an isotonic beverage or sports bar. Specifically, the composition contains 10 – 90 w % carbohydrate, 0.1 – 50 wt % peptide material and 0.2 – 20 wt % of each free amino acid. Applicant additionally claims a method of feeding and a method of enhancing blood insulin levels, the methods comprising administering the composition of claim 17, 36, 37 or 38 to a human.

Kahn teaches nutritional compositions containing casein and/or soy protein hydrolysates combined with whey protein hydrolysates and amino acids (abstract). The hydrolysates are obtained by hydrolysis of the protein (p.2 line 15-20). The whey protein hydrolysate comprises 40 – 60 wt % if its amino acids as oligopeptides having 4 – 10 amino acids (p.4 line 5-10). The amino acids are in free form and comprise less than 3.5 % by weight (p.5 line 14-20) and may include arginine, glutamine, leucine and phenylalanine (p.8 line 30-50). The composition further includes carbohydrates (particularly maltodextrines p.6 line 8-9), fatty acids (triglyceride oils and phospholipids, p.6 line 25), vitamins, minerals (p.5 line 54-56) and flavorants (p.6 line 53). The compositions are disclosed for enteral use as well as aqueous liquids, food supplements, complete diet and therapeutic nutrition (p.6 line 12-19).

Kahn does not teach the composition wherein the peptide is derived from wheat protein or further comprising lipid emulsifiers. However, Kingham teaches nutritional compositions containing a carbohydrate, a protein (or peptide material) and amino acids selected from

arginine, phenylalanine and leucine (abstract) wherein the protein source is selected from wheat, peas, beans, and milk (casein, whey) and is in the hydrolyzed form (p.8). The composition additionally contains a fat component wherein the fat is phospholipids, triacylglycerols or sterols (p.10), vitamins, minerals, flavoring agents, emulsifiers, and preservatives (p.12).

At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use peptides derived from wheat protein, since it was a well known source of peptides in the art, as demonstrated by Kingham. In addition, it would have been obvious to one of ordinary skill in the art to include emulsifiers in the composition so Kahn, since it was routine practice in the art as demonstrated by Kingham. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Kingham and routine practice to use whet derived proteins and include emulsifiers in the composition of Kahn with a reasonable expectation for successfully obtaining the nutritional composition of Kahn.

Kahn does not teach the composition comprising the specific amounts of carbohydrates, protein and amino acids or peptide chain lengths as claimed. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such variables as a matter of routine experimentation. Moreover, one of ordinary skill in the art would have been motivated by routine practice to optimize the volumes of Kahn with a reasonable expectation for obtaining a healthful, nutritious composition. Although the reference does not specifically teach a method for enhancing blood insulin levels, it was well known in the art that ingestion of carbohydrates, peptides and certain amino acids increase blood insulin levels (see Portman abstract). As such at the time of the invention, it would have been

obvious to one of ordinary skill in the art to use the composition of Kahn in a method to increase blood insulin levels with a reasonable expectation of success.

Applicant argues that Kahn does not teach adding additional free leucine and phenylalanine with the peptide material, but that the amino acids are present in the hydrolysate therefore there is no motivation to add additional amino acids. Applicant additionally argues a synergistic effect when the additional free amino acids are added to a wheat hydrolysate pointing to the third study in the specification.

However, these arguments fail to persuade because Kahn specifically teach free amino acids (p.5 line 14-20) including leucine and phenylalanine (p.8 line 30-50). In addition, at the time of the invention, free amino acids were known to stimulate glycogen synthesis (see Portman, abstract).

Regarding the synergistic effects, the claims do not include all of the limitations as described in the third study (i.e. wheat hydrolysate), and is therefore not commensurate in scope with the claims.

For theses reasons the claims remain rejected.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad
April 2, 2003

LEON B. LANKFORD, JR.
PRIMARY EXAMINER